

Attorney Docket No.: **NE-0004**  
Inventors: **Hollingsworth et al.**  
Serial No.: **10/618,481**  
Filing Date: **July 11, 2003**  
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**REMARKS**

Claims 1-3 are pending in this application. Claim 2 has been withdrawn from consideration. Claims 1 and 3 have been rejected. Claim 1 has been amended. The specification has been amended at page 28 to correct the inadvertent inclusion of hypertext. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of these amendments and the following remarks.

**I. Election/Restriction Requirement Under 35 U.S.C. §121**

The restriction requirement placing the instant claims into Groups I-II has been deemed proper and made final. Claim 2 has been withdrawn from further consideration.

**II. Rejections under 35 U.S.C. §102**

Claims 1 and 3 have been rejected under 35 U.S.C. 102(b) as being anticipated by Hoover et al. ((1993) *J. Clin. Oncol.* 11(3):390-9) as evidenced by Byrd ((2004) *Cancer and Metastasis Review* 23:77-99). The Examiner suggests that Hoover et al. describe clinical trials wherein patients with Dukes' B2 or C3 were treated with an autologous tumor-bacillus Calmette-Guerin (BCG) vaccine, wherein the autologous tumor cells of Hoover et al. would comprise a cytoplasmic tail peptide of SEQ ID NO:1 as evidenced by the teachings of Byrd et al. Applicants respectfully disagree with this rejection.

Hoover et al. disclose the use of autologous tumor cells combined with BCG in the treatment of colon and rectal cancer. Byrd

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et al. teach the expression of MUC1 in colorectal cancer. However, neither of these references teach or suggest an isolated MUC1 cytoplasmic tail peptide as is disclosed throughout the instant specification and in particular at page 18 (lines 11) to page 20 (line 7). Thus, in an earnest effort to clarify the instant composition, Applicants have amended claim 1 to indicate that the claimed composition comprises at least a portion of an isolated MUC1 cytoplasmic tail peptide of SEQ ID NO:1. Because Hoover et al. fail to teach such an isolated peptide, this reference cannot be held to anticipate the present invention. It is therefore respectfully requested that this rejection be reconsidered and withdrawn.

Claims 1 and 3 have also been rejected under 35 U.S.C. 102(e) as being anticipated by WO 02/058450. It is suggested that this reference teaches a composition comprising a polypeptide having the amino acid sequence of SEQ ID NO:1 of the instant application, a composition comprising a polypeptide having the amino acid sequence of amino acid residues 1 to 42 of SEQ ID NO:1 of the instant application, and a compositions comprising a polypeptide having the amino acid sequence of amino acid residues 22 to 72 of SEQ ID NO:1 of the instant application, all of which allegedly meet the limitation of at least a portion of MUC1 cytoplasmic tail peptide of SEQ ID NO:1.

Claims 1 and 3 have been rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,548,643. It is suggested that this reference teaches conjugates between an antigen and a carbohydrate polymer, wherein the conjugates may be immunogenic vaccines; and wherein the conjugates may contain one or more

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repeated subunits of human mucin or non-repeated regions of human mucin. It is further suggested that this reference teaches immunogenic peptides derived from the extracellular region or intracellular region of MUC1 and the preferred peptides comprise amino acids 1-21 or 35-54 of the intracellular portion of MUC1 (*i.e.*, of SEQ ID NO:1 of the instant application), which are at least a portion of the cytoplasmic tail.

Applicants respectfully disagree with these rejections.

The teachings of the prior art provide for peptides that inhibit the physical interaction between MUC1 and tumor progressors (WO 02/058450) and immunogenic conjugates composed of mannose and one or more non-repeated regions of human mucin (U.S. Patent No. 6,548,643). In contrast, Applicants disclose MUC1 peptides for eliciting an immune response to MUC1-expressing tumor cells. MUC1 peptides encompassed within the scope of "at least a portion of an isolated MUC1 cytoplasmic tail peptide of SEQ ID NO:1" are clearly disclosed in the instant specification in Tables 3-4 and in the paragraph bridging pages 17 and 18. Peptides set forth in SEQ ID NOS:3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, and 49 of Tables 3-4 and in the paragraph bridging pages 17 and 18 are neither taught nor suggested by the prior art cited by the Examiner as being relevant to a molecule comprising at least a portion a MUC1 cytoplasmic tail peptide of SEQ ID NO:1. Accordingly, in an earnest effort to distinguish the instant composition from the referenced teachings, Applicants have amended claim 1 to indicate that the portion of an isolated MUC1 cytoplasmic tail peptide of SEQ ID NO:1

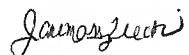
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is selected from the group consisting of SEQ ID NOS:3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, and 49 as supported by the paragraph bridging pages 17 and 18. Because the cited prior art references fail to teach or suggest the claimed peptides of SEQ ID NO:1, these references cannot be held to anticipate the present invention. It is therefore respectfully requested that these rejections be reconsidered and withdrawn.

### **III. Conclusion**

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



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